

REMARKS

Applicants respectfully request the issuance of a new paper in view of the Supplemental Amendment filed on April 26, 2004 in response to the Notice of Non-Compliant Amendment. A copy of the return postcard date stamped April 29, 2004 by the Patent Office is enclosed for your reference along with a copy of the papers filed.

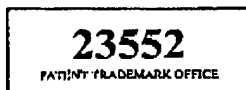
An early and favorable action on the merits is requested.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Any questions or concerns regarding this communication can be directed to the undersigned attorney, John J. Gresens, Reg. No. 33,112, at 612.371.5265.

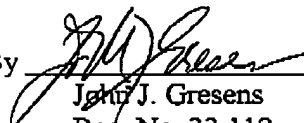
Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300



Dated: June 30, 2004

By


John J. Gresens
Reg. No. 33,112

JJG:mmm

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**RECEIVED**
CENTRAL FAX CENTER

Applicant: HANSEN et al. Examiner: Unknown
Serial No.: 10/727832 Group Art Unit: 1631
Filed: December 4, 2003 Docket: 12845.0002USC1
Title: Method And A System For Determination Of Particles In A Liquid Sample

JUN 3 0 2004

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 26, 2004.

By: A. Ewald
Name: A Ewald

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

23552
PATENT TRADEMARK OFFICE

OFFICIAL

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal Sheet in duplicate containing Certificate of Mailing
- ☒ Supplemental Amendment
- ☒ Other: Copy of Office communication entitled "Notice of Non-Compliant Amendment"
- ☒ Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

MERCHANT & GOULD P.C.
P.O. Box 2903, Minneapolis, MN 55402-0903
612.332.5300

By: J. J. Gressens
Name: John J. Gressens
Reg. No.: 33,112
JJG/ame

Receipt is hereby acknowledged for the following in the U.S. Patent and Trademark Office:
In re Application of: HANSEN et al.
For: Method And A System For Determination Of Particles In A Liquid Sample
Docket No.: 12845.0002USC1
Filed: December 4, 2003
Serial No.: 10/727832
Due Date:
Date Mailed: April 26, 2004
☒ Transmittal Sheet in duplicate containing Certificate of Mailing
☒ Supplemental Amendment
☒ Other: Copy of Office communication entitled "Notice of Non-Compliant Amendment"
☒ Return postcard

Patent



JJG/ame



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------|-------------------------|---------------------|------------------|
| 10/727,832 | 12/04/2003 | Ernas Ejner Rvan Hansen | 12845.0002USC1 ✓ | 7440 |
| 23552 7590 04/07/2004 | | | | |
| MERCHANT & GOULD PC | | | | |
| P.O. BOX 2903 | | | | |
| MINNEAPOLIS, MN 55402-0903 | | | | |
| JSG | | | | |
| EXAMINER | | | | |
| MERLINO, AMANDA H | | | | |
| ART UNIT | | | | |
| PAPER NUMBER | | | | |
| 2877 | | | | |

DATE MAILED: 04/07/2004

Response Due: May 7, 2004
JSG

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. Box 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

Paper No.

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment document filed on 12-4-03 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003 (see 68 Fed. Reg. 38611, Jun. 30, 2003). In order for the amendment document to be compliant, correction of the following item(s) is required. Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted. 37 CFR 1.121(h).

THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____
- ☐ 3. Amendments to the drawings: _____
- ☒ 4. Amendments to the claims:
- ☒ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all claims (including withdrawn claims)
 - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified.
 - ☒ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☒ E. Other: missing canceled claims 2-57

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/brocnnotice/officeflyer.pdf>.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT**, applicant is given **ONE MONTH** from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and this **ONE MONTH** time limit is not extendable.

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION** (including a submission for an RCE), and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(e)), applicant is given a **TIME PERIOD** of **ONE MONTH** from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION**, this form may be an attachment to an Advisory Action. The period for response to a final rejection continues to run from the date set in the final rejection, and is not affected by the non-compliant status of the amendment.

Carroll
Legal Instruments Examiner (LIE)

Telephone No. _____

Rev. 10/03

JUN 30 2004

OFFICIAL

S/N 10/727832

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|-------------|-----------------------------------------------------------------------|-----------------|----------------|
| Applicant: | HANSEN et al. | Examiner: | Unknown |
| Serial No.: | 10/727832 | Group Art Unit: | 1631 |
| Filed: | Concurrent herewith | Docket No.: | 12845.0002USC1 |
| Title: | Method And A System For Determination Of Particles In A Liquid Sample | | |

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 26, 2004.

By: Ashley Ewald

Name: A Ewald

SUPPLEMENTAL AMENDMENT

Mail Stop Patent Application

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

In connection with the above-identified application filed herewith, please enter the following preliminary amendment:

Please insert the **Abstract** page beginning on page 10 into the application as the last page thereof.

Amendments to the claims are reflected in the listing of claims which begins on page 2 of this paper

Remarks begin on page 11 of this paper.

Amendments to the claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-57. (cancelled)

58. (new) A method for the assessment of at least one quantity parameter and/or at least one quality parameter of bacteria in a liquid analyte material, comprising

applying a volume of a liquid sample representing the analyte material, or bacteria isolated from a volume of liquid sample representing the analyte material, to an exposing domain from which exposing domain electromagnetic signals from the sample in the domain can pass to the exterior,

exposing, onto an array of active detection elements, an at least one-dimensional spatial representation of electromagnetic signals having passed from the domain, the representation being one which is detectable as an intensity by individual active detection elements, under conditions which will permit processing of the intensities detected by the array of detection elements during the exposure in such a manner that representations of electromagnetic signals from the bacteria are identified as distinct from representations of electromagnetic signals from background signals, and wherein the spatial representation exposed onto the array of detection elements is subject to such a linear enlargement that the ratio of the image of a linear dimension on the array of detection elements to the original linear dimension in the exposing domain is smaller than 10:1,

processing the intensities detected by the detection elements in such a manner that signals from the bacteria are identified as distinct from background signals,

and correlating the results of the processing to the at least one quantity parameter and/or the at least one quality parameter of the liquid analyte material.

59. (new) A method according to claim 58, wherein the electromagnetic signals comprise chemoluminescence, photoluminescence, fluorescence or phosphorescence.

60. (new) A method according to claim 58, wherein the sample compartment has a wall part defining an exposing area, the wall part allowing electromagnetic signals from the sample in the compartment to pass through the wall and to be exposed to the exterior.

61. (new) A method according to claim 58, wherein the image of the electromagnetic signals is a one-dimensional image.

62. (new) A method according to claim 58, wherein the image of the electromagnetic signals is a two-dimensional image .

63. (new) A method according to claim 58, wherein the array of detection elements is arranged in such a way that a series of detection elements form a substantially straight line.

64. (new) A method according to claim 6, wherein the array of detection elements is arranged in two directions in such a way that the detection elements form a series of substantially parallel straight lines, the series forming a rectangle.

65. (new) A method according to claim 58, wherein the exposure of the image of electromagnetic signals onto the array of detection elements is performed by focusing an image of electromagnetic signals from at least a part of the exposing domain onto the array of detection elements by means of a focusing means.

66. (new) A method according to claim 65, wherein the focusing means is a lens consisting of one or several elements.

67. (new) A method according to claim 58, wherein the individual bacteria the parameter or parameters of which is/are to be assessed are imaged on at the most 5 detection elements.

68. (new) A method according to claim 58, wherein the interior of the sample compartment has an average thickness of between 20 μm and 200 μm .

69. (new) A method according to claim 58, wherein the sample compartment has dimensions, in a direction substantially parallel to the array of detection elements, in the range between 1 mm by 1 mm and 10 mm by 10 mm.

70. (new) A method according to claim 58, wherein the volume of the liquid sample from which electromagnetic radiation is detected on the array is in the range between 0.01 μl and 20 μl .

71. (new) A method according to claim 70, wherein the volume of the liquid sample from which electromagnetic radiation is detected on the array is in the range between 0.01 μl and 1 μl .

72. (new) A method according to claim 58, wherein the sample in the sample compartment is at stand still during the exposure.

73. (new) A method according to claim 58 wherein the sample in the sample compartment is moved through the sample compartment during the exposure, and wherein the exposure is performed over a sufficiently short period of time so substantially obtain stand still condition during the exposure.

74. (new) A method according to claim 58, wherein at least a major part of the electromagnetic radiation emitted from the sample during exposure originates from or is caused by electromagnetic radiation supplied to the sample from a light source, at least a

major part of the radiation from the light source having a direction which is transverse to the wall of the sample compartment or a plane defined by the compartment.

75. (new) A method according to claim 58, wherein the parameter to be assessed is the number of the bacteria per volume of the liquid analyte material.

76. (new) A method according to claim 58, wherein the parameter(s) to be assessed is the size and/or shape of the bacteria in the liquid analyte material.

77. (new) A method according to claim 75, wherein the size of the volume of the liquid sample is sufficiently large to allow identification therein of at least 100 of the bacteria.

78. (new) A method according to claim 58, comprising

applying a volume of between 0.01 μ l and 20 μ l of a liquid sample representing the liquid analyte material, or bacteria isolated from a volume of a liquid sample representing the liquid analyte material, to the sample compartment the sample in the sample compartment being at stand still during the exposure, and in the case where at least a major part of the electromagnetic radiation emitted from the sample during exposure originates from or is caused by electromagnetic radiation supplied to the sample from a light source, then at least a major part of the radiation from the light source having a direction which is transverse to the wall of the sample compartment or a plane defined by the compartment, and

the individual bacteria the parameter or parameters of which is/are to be assessed are imaged on at the most 25 detection elements of the array of detection elements.

79. (new) A method according claim 58, wherein the parameter to be assessed is the presence or non-presence of a particular type of bacteria in the liquid analyte material.

80. (new) A method according to claim 58, wherein bacteria isolated from a liquid sample representing the analyte are applied to the sample compartment or arranged in the sample compartment, the bacteria being retained on a bacterium retaining means selected from means chemically binding the bacteria, means capable of electronically or magnetically retaining the bacteria, and filtering means.

81. (new) A method according to claim 58, wherein the signal which is detected by the detecting elements originates from one or several types of molecules of types which bind to, are retained within, or interact with, the bacteria, such molecules being added to the sample or the isolated bacteria before or during exposure, the molecules being molecules giving rise to one or several of the following phenomena: attenuation of electromagnetic radiation, photoluminescence when illuminated with electromagnetic radiation, scatter of electromagnetic radiation, raman scatter.

82. (new) A method according to claim 81, wherein an effective amount of one or more nucleic acid dyes and/or one or more potentiometric membrane dyes is added.

83. (new) A method according to claim 58, wherein the duration of the exposure is in the range from 100 milliseconds to 5 seconds.

84. (new) A method according to claim 83, wherein the duration of the exposure is in the range of 0.5 to 3 seconds.

85. (new) A method according to claim 83, wherein the exposure is performed as a single exposure.

86. (new) A method according to claim 58, wherein compression of information of the intensities representing distinct objects scattered over an area, an object being represented by a variation in the intensity information

- said information existing in the form of varying degrees of measurable intensity of a physical property distributed over a confined area divided into sub-areas, each of which sub-areas having assigned thereto an index uniquely identifying the sub-area,

the method comprising

- determining the intensity of the physical property ,

a) defining a sub-area of interest situated in a group of sub-areas comprising of at least 2x2 sub-areas situated adjacent to each other,

b) evaluating in said sub-area of interest at least one directional derivative(s) of the measurable intensity in the sub-area of interest with respect to predetermined geometrical direction(s) in the plane of the confined area, the directional derivative(s) is (are) based on measurable intensities in sub-areas situated adjacent to or in proximity of the group of sub-area,

c) based on the evaluation of the at least one directional derivative an attribute is assigned to the value assigned to said sub-area of interest; the attribute represent an adjusted measurable intensity and/or information(s) related to a predetermined strategy for adjustment of the measurable intensity in the sub-area of interest or sub-areas situated adjacent to or in proximity to the sub-area of interest,

d) repeating the step a) - c) for substantially all sub-areas of the confined area.

87. (new) A method according to claim 58, wherein the correlation comprises:

- identifying and counting substantially all detection elements having intensities which are distinct from background signals,
- adjusting the result of the counting by a predefined scaling value,

- the scaling value being directly related to the number of detection elements representing a signal from a bacterium,
- the result of the scaling being correlated to the number of bacteria represented exposure.

88. (new) A method according to claim 87, where the measured intensities of the detection elements have been adjusted prior to counting, the adjustment comprising the steps of:

- a) defining a range of a predetermined size in a co-ordinate system representing the intensity values of the detection elements, the size of the range being determined such that it is bigger than the representation of a bacterium having an average extension,
- b) choosing a first detection element, the first detection element being one of which the intensity is subject to an adjustment,
- c) positioning the range such that the detection element of which the intensity is to be adjusted is substantially in the centre of the range,
- d) adjusting the intensity of the detection element in the centre of the range based on the result of an investigation of at least one gradient describing the variation of the signal intensities inside the range and around the centre of the range by considering intensities of detection elements describing the gradient,

and repeating the step b) through c) until a predetermined number of detection elements has been adjusted a predetermined number of times.

89. (new) A method according to claim 58, wherein the sample compartment from which electromagnetic signals from the sample in the sample compartment can pass to the

exterior is adapted to allow the assessment of substantially only one sample of liquid analyte material.

90. (new) A method according to claim 89, wherein the sample compartment is connected with a reagent container, the reagent container containing one or several reagent component(s).

91. (new) A method according to claim 90, wherein the reagent container contains one or several reagent component(s) in an amount substantially adequate for substantially only one assessment.

Abstract

The present invention relates to a method for the assessment of quantity and quality parameters of biological particles in a liquid analyte material. The method comprises applying a volume of a liquid sample to an exposing domain from which exposing domain electromagnetic signals from the sample in the domain can pass to the exterior, and exposing, onto an array of active detection elements such as CCD-elements, a spatial representation of electromagnetic signals having passed from the domain, the representation being detectable as an intensity by individual active detection elements, under conditions permitting processing of the intensities detected by the array of detection elements during the exposure in such a manner that representations of electromagnetic signals from the biological particles are identified as distinct from representations of electromagnetic signals from background signals. The size of the volume of the liquid sample is sufficiently large to permit the assessment of the quantity and quality parameters to fulfill a predetermined requirement to the statistical quality of the assessment based on substantially one exposure.

Remarks

The above preliminary amendment is made to cancel claims 1-57 and add claims 58-91, in compliance with the Notice of Non-Compliant Amendment communication mailed April 7, 2004.

A courtesy copy of the present specification is enclosed herewith. However, the World Intellectual Property Office (WIPO) copy should be relied upon if it is already in the U.S. Patent Office.

A new abstract page is supplied to conform to that appearing on the publication page of the WIPO application, but the new Abstract is typed on a separate page as required by U.S. practice.

Applicants respectfully request that the preliminary amendment described herein be entered into the record prior to calculation of the filing fee and prior to examination and consideration of the above-identified application.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' primary attorney-of record, John J. Gresens (Reg. No. 33,112), at (612) 371-5265.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300



Dated: April 26, 2004

JJG/ame

By

A handwritten signature in dark ink, appearing to read 'John J. Gresens'. Below the signature, the name 'John J. Gresens' and the registration number 'Reg. No. 33,112' are printed in a sans-serif font.
John J. Gresens
Reg. No. 33,112